

**K854314 FANA 60**Dec 16, 1985  
49 days to decisionK854314 · Product code: **DHN** · Immunology  
Source: <https://www.510kdatabase.net/k854314/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Oct 28, 1985
Decision date	Dec 16, 1985
Days to decision	49 days
Third-party review	No

**APPLICANT**

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Company	<b>American Bio-Reagents, Inc.</b>
Location	Easton, PA, US
Contact	DAVID E KOLESAR
510(k) history	1 submissions · 1 cleared · 1985-1985

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